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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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RISSMAN JOBSE HENDRICKS & OLIVERIO, LLP
ONE STATE STREET
SUITE 800
BOSTON, MA 02109

EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,618	GESTRELIUS ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 50-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 50-66 is/are rejected.

7)☒ Claim(s) 50 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendment submitted 10/30/2003, which cancelled claims 1-49 and submitted new claims 50-66, has been received and entered into the case. Claims 50-66 are pending in the current application, all of which have been considered on the merits.

Priority

Applicant's claim for priority under 35 USC 121, as a divisional of application 10/156,300 (now US Patent 6,720,009) is acknowledged. US application 10/156,300 (USP 6,720,009) is a divisional of application 09/258,613 (now US Patent 6,503,539), which further claims priority to us provisional application 60/081,551, filed 13 April 1998. Support for the current claims is found in all parent applications, as such the effective filing date of the claims is considered to be 13 April 1998.

Claim Objections

Claim 50 is objected to because of a spelling error: "prophylactically" is incorrectly spelled "prphylactically" in the second line of the claim. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to methods of preventing or treating an inflammatory condition or for preventing or treating an infection, each method comprising administering to a mammal in need thereof a prophylactically or therapeutically effective amount of an active enamel substance, wherein the active enamel substance is selected from the group consisting of enamelins, amelogenins, non-amelogenins, proline-rich non-amelogenins, amelins (ameloblastin, sheathlin), tuftelins, and derivatives thereof and mixtures thereof.

It has been held that "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention... one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process." MPEP § 2163

Regarding the term "derivatives thereof" as one of the possible compounds for administration to the mammal in need thereof, due to the great number and variety of compounds included in the scope of "derivatives of enamelins, amelogenins, non-amelogenins, proline-rich non-amelogenins, amelins (ameloblastin, sheathlin), and tuftelins" applicants are not found to be in possession of a representative number of species that sufficient represent the great variety of such compounds, which is required to claim all derivatives of each of the named compounds. In giving the term 'derivatives thereof' its broadest reasonable interpretation, the number and types of compounds which can be considered derivatives of enamelins, amelogenins, non-amelogenins, proline-rich non-amelogenins, amelins (ameloblastin, sheathlin), and tuftelins is extraordinarily great, and can be interpreted to even include elemental carbon, nitrogen and hydrogen as derivatives of each of the compounds. Applicants have not specifically defined

what characteristics of each of the compounds listed the claimed "derivatives thereof" must have; applicants have not identified any particular core chemical structure or function of each of the compounds which must be shared by all derivatives thereof; and thus one of ordinary skill in the art would not immediately envisage all derivatives of each of enamelins, amelogenins, non-amelogenins, proline-rich non-amelogenins, amelins (ameloblastin, sheathlin), and tuftelins. Therefore, it is not clear which derivatives of each of the named compounds are to be included in the scope of the claim, and which are not.

Claims 50-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating an inflammatory condition located in the oral cavity, does not reasonably provide enablement for preventing any and all inflammatory condition and/or treating any inflammatory condition not associated with the oral cavity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without undue or unreasonable experimentation. See *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). The key word is 'undue,' not experimentation.' " (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the

invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 50-53 are drawn to a method of preventing and treating inflammation, thus the scope of the claims includes any and all types of inflammation, in any area of the mammalian body, brought on by any cause. While the person of ordinary skill in the art, based on the teachings and knowledge generally available to the skilled artisan, as well as based on the teachings and experiments provided in the instant specification, would have a reasonable expectation of successfully treating inflammation in the oral cavity, caused by infection, oral surgery or other physical damage to the oral cavity, as well as symptoms associated with such inflammation by administering the active enamel substances disclosed in the present application, he or she would not have such an expectation for preventing inflammation in general or for treating inflammation in any other area of the mammalian body. Inflammation is a natural defense and repair mechanism of the body, it is required for healing wounds and destroying infections within the body. Inflammation is not limited to external wounds, but occurs frequently internally, for example, the body fights infection by invading pathogens (a desirable, and necessary response); or in the case of asthma, wherein the airways become inflamed and constrict in response to pathogenic or non-pathogenic triggers, such as allergens, temperature, or even stress (a non-desirable, but chronic and recurrent response).

The examples provided in the specification are limited to treatment of oral wounds caused by oral trauma (tooth extraction, oral ulcer, etc) or infection of such wounds; application of EMDOGAIN (active enamel substance) is reported to reduce the incidence of inflammation resulting from infection (as EMODGAIN is reported to inhibit microbial growth) as well as reducing swelling associated with suturing (as EMODGAIN is reported to hasten the healing process). Thus, while the active enamel substance has been shown reduce (treat) inflammation in oral wounds caused by either infection or physical trauma (e.g. surgery, suturing, etc), there is not sufficient evidence or teachings to support the

claim that the active enamel substances of the instant invention can effectively prevent any and all inflammation or even treat (reduce) inflammation not associated with the oral cavity. The specification does not provide teachings or guidance on how the active enamel substance can be delivered internally to treat inflammatory conditions present inside the body (i.e. inflammation of bronchial tubes during asthma attacks, inflammation of the pancreas during bouts of pancreatitis, inflammation of the brain caused by encephalopathy) which would be included in the scope of treating all inflammatory conditions in a mammalian body.

While lack of working embodiments that sufficiently cover the entire scope of the claim cannot be a sole factor in determining enablement, the absence of substantial evidence, in light of the unpredictable nature of the art and the direction applicants present, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole. Thus one of ordinary skill in the art would not have a reasonable expectation of successfully preventing any and all inflammations, nor a reasonable expectation of successfully treating inflammations except those present in the oral cavity by performing the claimed method.

Claims 54-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating an infection, does not reasonably provide enablement for preventing any and all infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without undue or unreasonable experimentation. See *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). The key word is 'undue,' not experimentation.' " (Wands, 8 USPQ2d 1404). The factors to

be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claims 54-66 are drawn to a method of preventing and treating infections, thus the scope includes all types of infections caused by any and all pathogens. While the person of ordinary skill in the art, based on the teachings and knowledge generally available to the skilled artisan, as well as based on the teachings provided in the instant specification, would have a reasonable expectation of successfully treating infections and the symptoms associated with said infections by administering the active enamel substances disclosed in the present application, he or she would not have such an expectation for preventing the actual infections. An infection is simply an invasion by pathogenic microorganisms (See "infection" *The American Heritage® Stedman's Medical Dictionary*, retrieved from Dictionary.com). Because the body is constantly covered with, and surround by, bacteria it is impossible to ensure that not a single bacterial microbe would enter the body and multiply even once, which would constitute "infection." Rather, it would be more appropriate to limit the claims to method of treating infections.

Additionally, the applicants have provided no direction for the claimed method to prevent any and all infections. The experiment provided in the specification demonstrates the ability of EMDOGAIN (active enamel substance) to inhibit growth of several microbial species, including *E. coli, Staphylococcus aureus, Bacillus subtilis,* and *Candida albicans* after a two or five day *in vitro* incubation period (See spec, pg. 42, Table 1); no long term *in vivo* results are provided showing patients who receive the active enamel substance never acquire an infection, as would be required to support the "prevention" claim. While lack of a working embodiment cannot be a sole factor in determining enablement, the absence of

substantial evidence, in light of the unpredictable nature of the art and the direction applicants present, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole. Thus one of ordinary skill in the art would not have a reasonable expectation of successfully preventing gastrointestinal tract infections and urinary tract infections caused by the cited microbes by performing the claimed method.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-53 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 51 and 55 the term "derivatives thereof" renders the claims indefinite, as it is not clear which derivatives of enamelins, amelogenins, non-amelogenins, proline-rich non-amelogenins, amelins (ameloblastin, sheathlin), and tuftelins are to included in the claim, as applicants have not defined any particular core structure of each of the active enamel substances which must be shared by all of the derivatives.

The language of claims 52-53 and 55 are indefinite because each claim recites a broad range or limitation together with a narrower range or limitation that falls within the broad range; as such, it is not clear which, if any, actually limit the claim. It has been held that recitation of a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation is considered indefinite as it fails to set forth the metes and bounds of the patent protection desired, see *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989) and MPEP § 2173.05(c).

Specifically, in claim 51 the broad limitation is amelins, and the narrower limitations are the recitation of the specific species of ameloblastin and sheathlin; it is not clear if each of these species are to be included, or if they are merely examples.

In claim 52 the broad range is "wherein the active enamel substance has a molecular weight of at most about 120 kDa" and the recited narrower ranges are "*such as*, at the most 100 kDa, 90 kDa, etc;" it is not clear which range actually limits the claimed method.

In claim 53 the broad range is a protein concentration of "from about 0.01 mg/cm^2 to about 20mg/cm^2" and the narrower range is "such as from about 0.1 mg/cm^2 to about 15 mg/cm^2;" again it is not clear which protein concentration limits the claimed method

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-52, 54, 55, 57, 59, 60 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammarstrom et al (US Patent 5,071,958).

Applicants' claims are directed to methods of preventing or treating an inflammatory condition and/or an infection, comprising administering to a mammal in need thereof a prophylactically or therapeutically effective amount of an active enamel substance. Dependent claims require the active enamel substance to be selected from the group consisting of enamelins, amelogenins, non-amelogenins, proline-rich non-amelogenins, amelins, such as ameloblastin and sheathlin, tuftelins and derivatives thereof and mixtures thereof. Other dependent claims require the active enamel substance to have a molecular weight of at the most about 120 kDa such as, e.g., at the most 100 kDa, 90 kDa, 80 kDa, 70

kDa, or 60 kDa as determined by SDS Page electrophoresis. Some dependent claims require the infection to be a bacterial infection of the oral cavity. Some dependent claims require the active enamel substance to be administered to any one of a variety of sites, including an internal wound. Some dependent claims require the active enamel substance to be provided as an implant or a coating of an implant.

Hammarstrom et al disclose a process for inducing binding between mineralized living tissues, particularly for inducing binding between a tooth and the jaw bone for the treatment of periodontitis. Specifically, Hammarstrom et al apply a composition comprising active enamel matrix proteins to a loose or removed tooth; Hammarstrom et al disclose the active enamel matrix protein composition induces fomration of root cementum and collagen fibers, thereby reattaching the tooth to the jaw bone (See Hammarstrom et al, col. 4, ln 20-37). Note: in situations where the tooth is loose in the gum cavity, the composition is applied directed to the cavity, which is considered to be an 'internal wound;' in situations where the tooth is removed from mouth, the tooth is considered to be an implant, thus applying the enamel matrix composition to the tooth reads on coating an implant with the enamel matrix composition.

Regarding the active enamel matrix protein composition, Hammarstrom et al isolate and characterize nine separate protein extracts (See Hammarstrom et al, col. 6, ln 3-54). Fraction E3 was found to be the most effective at inducing formation of new cementum, periodnotal membrane and alveolar bone (See col. 7, ln 27-47 & Table 1), and thus was further characterized. Further analysis showed fraction E3 contained enamalins (MW >40 kDa), high molecular weight amelogenins (MW 25 kDa), intermediate weight amelogenins (MW 14 kDa) and low molecular weight amelogenins (MW 5-10 kDa) (See col. 8, ln 10-36).

Therefore, the method of Hammarstrom et al comprises administering what is being considered an effective amount of a composition comprising enamelins and amelogenins (MW ranging from 5-40 kDa) to a tooth and/or tooth socket of a mammal experiencing periodontitis. Though Hammarstrom et al do not specifically teach application of the enamel matrix protein composition prevents an inflammatory

condition and/or an infection, the method of Hammarstrom et al is one and the same as those currently claimed; and thus the method of Hammarstrom et al would inherently prevent inflammatory conditions and/or infections, including bacterial infections, in the mouth (where the composition is applied). Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art method. When the prior art method is the same as a method described in the specification for carrying out the claimed method, it can be assumed the method will inherently perform the claimed process. See *In re Best*, 562 F. 2d, 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) and *Ex parte Novitski*, 26 USPQ 2d 1389 (Bd. Pat. App. & inter. 1993). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of the invention, but only that the subject matter is in fact inherent in the prior art reference. See *Schering Corp. v. Geneva Pharm. Inc*, 339 F.3d 1373, 1377, 67, USPQ2d 1664, 1668 (Fed. Cir. 2003). See also *Toro Co. v. Deere & Co.* 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004). Please note, the method of Hammarstrom et al only reads on "preventing" the inflammatory condition and/or infection, as Hammarstrom et al do not teach applying the composition to an oral site that exhibits inflammation and/or infection, thus the method of Hammarstrom et al cannot be considered to "treat" inflammatory conditions and/or infections.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 54-66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 13-19 of U.S. Patent No. 6,720,009. Claims 54-66 of the instant application are identical to claims 1-6 and 13-19 of US Patent 6,720,009, except that the current claims recite the method is effective to treat *and prevent* infection, whereas the patented claims are limited to treatment of infection. Thus, while the current claims are broader in scope than the patent claims, the patented claims do anticipate at least the treatment part of the current claims, therefore rendering the current claims unpatentable over the claims of US Patent 6,720,009.

However, it is further noted that the instant claims are not enabled for a method of *preventing* an infection, as set forth above; thus, if the current claims 54-66 were limited to a method of treating an infection, then the claims would be identical to claims 1-6 and 13-19 of US Patent 6,720,009 and as such would be rejected under 35 USC 101 as claiming the same invention as US Patent 6,720,009, this would be a double patenting rejection. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651